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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,042	09/29/2006	David Teh-Wei Chou	1034477-000016	8233

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EXAMINER

ZAREK, PAUL E

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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07/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/570,042	Applicant(s) CHOU ET AL.	
	Examiner Paul Zarek	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 6 and 18 have been amended by the Applicant in correspondence filed on 04/02/2009. Claims 1-7 and 10-18 are currently pending. This is the second Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

2. Claim 18 was objected to as being dependent upon a rejected base claim. This objection is moot in light of Applicants' amendment to Claim 18. Claim 18 is allowable.

3. Claims 1-6 and 10-17 were rejected under 35 U.S.C. 112, first paragraph, because the specification was not enabling for the entire scope of compounds of formula (I). Applicants traversed this rejection on the grounds that the specification and the state of the art would enable one of ordinary skill in the art to make the entire scope of compounds of formula (I). Applicants point to specific locations within the specification for support. Applicants further submit that the compounds of formula (I) are superior to 5-substituted-oxyalkylaminopyrazole compounds known in the prior art. Examiner respectfully disagrees.

4. Applicant provides generic disclosure for one of ordinary skill in the art to make the full scope of the compounds of formula (I) claimed. The availability of the starting material that is needed to prepare the invention as claimed is at issue here (MPEP §2164.01(b)). "A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area,

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this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).” The disclosures of Kando, et al. (US Patent No. 6,316,477, 2001, already of record), Phillips, et al. (European Patent No. 0 500 209, 1997, already of record), Jensen-Korte, et al. (US Patent No. 4,971,989, 1990, already of record), Manning, et al. (International Application No. WO98/28279, 1998, already of record) and Wu and Pilato (US Patent No. 5,691,333, 1997, already of record) demonstrate the variability permitted in R^1 , R^2 , R^3 , R^4 , R^5 , and R^6 , but do not disclose such a vast and broad scope as Applicants claim, herein. The generic teaching of the specification coupled by the dearth of guidance in the prior art are not considered sufficient to enable an art worker to make the entire scope of compounds of formula (I). The presence of secondary considerations, such as the use of an oral formulation, is not relevant to enablement rejection. Therefore, the rejection of Claims 1-6 and 10-17 under 35 U.S.C. 112, first paragraph, is maintained.

5. Claim 10, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kando, et al. (above) in view of Phillips, et al. (above), Jensen-Korte, et al. (above), Manning, et al. (above), Wu and Pilato (above), and King (Medicinal Chemistry: Principles and Practice, 1994, already of record). Applicants traversed this rejection on the grounds that the prior art does not fairly suggest the claimed invention. Specifically, Applicants assert that the novel

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compounds of formula (I) possess properties that are absent in the compounds disclosed in the prior art, such as the ability of putting the instantly claimed compounds in an oral dosage form. Applicants further assert that the compounds of the prior art (e.g. Kando, et al.) do not relate to those instantly claimed. To wit, the prior art compounds do not contain the C5 moiety --OC(=O)OR that renders the instantly claimed compounds novel. Applicants also submit that none of the references, except Jensen-Korte, et al., disclose that the compounds disclosed are effective against fleas. Respectfully, Examiner finds Applicants' argument unpersuasive.

6. The presence of the --OC(=O)OR , indeed, renders the instantly claimed compounds novel. However, each of the applied references, except King, disclose 5-substituted oxyalkylaminopyrazole compounds as pesticides, that can be effective against insect pests (Jensen-Korte, et al., col 5, lines 35-39; Wu and Pilato, col 1, lines 13-15; Kando, et al., abstract, Manning, et al., pg 1, lines 23-27; and Phillips, pg 1, lines 3-7). Moreover, Applicants admit that all compounds comprising a 5-substituted-oxyalkylaminopyrazole core are obvious variants of each other (reply filed 04/02/2009, pg 13, para 3, lines 8-10). The 5-substituted-oxyalkylaminopyrazoles of the prior art have the same utility (e.g. pesticide) as the instantly claimed compounds, thus it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the claimed compounds to control pests. Assertions that the claimed compounds are superior to those of the prior art because they are orally therapeutic are not persuasive because the instant claims recite no limitations requiring oral administration. "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)" (MPEP § 2145(VI)). Therefore, the rejection of Claims 10, 11, 13, and

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14 under 35 U.S.C. 103(a) as being unpatentable over Kando, et al., in view of Phillips, et al., Jensen-Korte, et al., Manning, et al., Wu and Pilato, and King is maintained.

7. Below are listed new grounds of rejection that are not necessitated by amendment to the claims. Therefore, this office action is considered non-final.

Claim Rejections - 35 USC § 112 (1st paragraph)

8. The text of Title 35, U.S.C. § 112, first paragraph, can be found in a prior Office action.

9. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I), or composition thereof, wherein:

R¹ is -CN;

R² is a halogen;

R³ is -CF₃;

R⁴ is -CH₃;

R⁵ is -CH₃, -CH₂CH₃, isopropyl, -CH₂CH=CH₂, phenyl, 4-trifluorophenyl, 4-methylphenyl, 4-nitrophenyl, 4-methoxyphenyl, 4-ethoxyphenyl, 2,6-difluorophenyl, 2-fluorophenyl, 4-chlorophenyl, 1-methylene-2-fluorophenyl, 1-methylene-4-chlorophenyl, or 1-methylene-4-methylphenyl;

R⁶ is -CF₃;

A is -CH₂CH₂-;

W is CCl;

X is C=O or SO₂; and

Y is a covalent bond, -O-, or -NH-,

10.

and a method of making and using said compounds and compositions, does not reasonably provide enablement for all other compounds encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 7

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was inadvertently omitted from the statement of rejection in Office Action mailed on 12/11/2008. The rejections of Claims 1-6 and 10-17 are hereby applied to Claim 7.

Conclusion

11. Claims 1-7 and 10-17 are rejected. Claim 18 is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/

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Primary Examiner, Art Unit 1617